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EXAMINER

KERR, KATHLEEN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

23

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/699,136

Applicant(s)

SANTI ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1, 17, 24 and 26-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 17, 24 and 26-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/14/02 and 9/5/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

Art Unit: 1652

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action (Paper No. 17 mailed September 19, 2002), Applicants filed a request for continued examination (RCE) and an amendment (Paper Nos. 20 and 21). Said amendment cancelled Claim 40 and amended Claims 1, 24, and 28-39. Thus, Claims 1, 17, 24, and 26-39 are pending in the instant application and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/161,703 filed on October 27, 1999.

### ***Drawings***

3. As previously noted, the drawing (Figure 1) has been approved by the Draftsmen and is, therefore, entered as a formal drawing acceptable for publication upon the identification of allowable subject matter.

4. The drawings filed on May 14, 2002 (Figures 2-9) (received and entered September 17, 2002, Paper No. 15) and on September 5, 2002 (amended Figure 4) (Paper No. 22) are considered informal for the reasons detailed in the attached copy of PTO Form 948. Appropriate correction is required in response to the instant Office action and may not be held in abeyance (see 37 C.F.R. § 1.85(a)).

***Withdrawn - Objections to the Specification***

5. Previous objection to the specification for containing incorrect priority data in the first lines of the specification is withdrawn by virtue of Applicants' amendment.
6. Previous objection to the specification for references to locations of graphs and figures throughout the specification is withdrawn by virtue of Applicants' amendment.
7. Previous objection to the amendment filed May 14, 2002 (Paper No. 10) under 35 U.S.C. § 132 for introducing new matter into the disclosure is withdrawn by virtue of Applicants' amendment.

***Withdrawn - Claim Objections***

8. Previous objection to Claims 30, 34, and 38 for containing new matter is withdrawn by virtue of Applicant's amendment.
9. Previous objection to Claims 30, 34, and 38 for a typographical error is withdrawn by virtue of Applicants' amendment.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

10. Previous rejection of Claims 1, 17, and 26-35 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "for biosynthesis of a polyketide produced by a modular polyketide synthase (PKS) produced by a PKS gene or genes in said host cell" is withdrawn by virtue of Applicants' amendment.

Art Unit: 1652

11. Previous rejection of Claims 24 and 36-39 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “wherein said genes produce enzymes capable of making S-methylmalonyl CoA, and a modular polyketide synthase (PKS) gene” is withdrawn by virtue of Applicants’ amendment.

12. Previous rejection of Claims 28, 29, 32, 33, 36, and 37 under 35 U.S.C. § 112, second paragraph, as being unclear as to how said mm-CoA mutase gene (singular) can be two genes – mutA and mutB – is withdrawn by virtue of Applicants’ amendment.

13. Previous rejection of Claims 28, 29, 32, 33, 36, and 37 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrases “**the** *Propionibacterium shermanii* methylmalonyl CoA mutase gene” and “**the** *Streptomyces cinnamonesis* methylmalonyl CoA mutase gene” (emphasis added) is withdrawn by virtue of Applicants’ amendment.

14. Previous rejection of Claims 30, 34, and 38 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “from a gene of an *E. coli* phage” is withdrawn by virtue of Applicant’s amendment. Applicants’ note that the Examiner considered the phrase “an *E. coli* gene” to encompass a “gene from an *E. coli* phage”; this is not entirely the case. As noted in the previous rejection, phrases like ---an *E. coli* gene--- are limited to endogenous *E. coli* genes while phages *E. coli* DNA can be virtually any recombinant DNA. The former interpretation is enforced in the instant claims, which are clear with such a definition.

Art Unit: 1652

15. Previous rejection of Claims 31, 35, and 39 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "PKS gene is a gene that encodes a 6-dEB synthase protein" is withdrawn by virtue of Applicants' amendment.

16. Previous rejection of Claims 30, 34, and 38 under 35 U.S.C. § 112, first paragraph, new matter, is withdrawn by virtue of Applicants' amendment.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

17. Previous rejection of Claims 1, 17, 24, and 26-39 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the reasons below. The previous rejection is reiterates as follows:

"Claims 1, 17, 24, and 26-39 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner notes that Claims 28, 29, 32, 33, 36, and 37 are included in the instant rejection based on the lack of clarity of the instant claims as noted above. Claims 1 and 24 are drawn to *E. coli* bacteria that express any *P. shermanii* or an *S. cinnamomensis* methylmalonyl CoA mutase gene that is claimed solely by function and without any structural limitations. Claims 1 and 24 also require that the *E. coli* bacteria express any *P. shermanii* epimerase gene that is claimed solely by function and without any structural limitations.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common

Art Unit: 1652

characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, a *P. shermanii* gene encoding methylmalonyl CoA mutase is described according to Marsh *et al.*, and a *S. cinnamonensis* genes encoding methylmalonyl CoA mutase is described according to Birch *et al.* (see page 15). Having only a single gene from each species, one of skill in the art would be unable to predict the structure of any other members of the claimed genus. In the instant specification, a *P. shermanii* gene encoding an epimerase is described according to Leadlay *et al.* (see page 18). Having only a single gene, one of skill in the art would be unable to predict the structure of any other members of the claimed genus. Therefore, claims drawn to bacteria containing the genus of said genes are also not adequately described."

Applicants argue that the specification adequately describes any *P. shermanii* or *S.*

*cinnamonensis* mutA and mutB genes as well as any *P. shermanii* epimerase genes by virtue of the examples of the cloning of particular genes in the above genera. While the Examiner does not disagree that Applicants are in the possession of species of the claimed genera, said species does not adequately describe the structure of the other members of the genera, as previously noted. Applicants argue that the Examiner has "doubted" the instant specification. This is not the case. The Examiner has specifically noted that Applicants have used particular species of the genes in the instant claims and that said species do not adequately describe their related genera. Applicants also argue that the Lily case gives credence to their arguments; however, here, just as in Lily, the name "rat cDNA encoding insulin" is insufficient to adequately describe the claimed genus.

Applicants argue that the pending claims now refer only to genes published in scientific journals or disclosed in the specification; this is not the case. The instant claims, as broadly but reasonably interpreted, are drawn to **any** *P. shermanii* or an *S. cinnamonensis* mutA and mutB genes and **any** *P. shermanii* epimerase gene. The pending claims are NOT limited to those

Art Unit: 1652

specifically disclosed in the art. To provide such a limitation, the Examiner suggests inserting SEQ ID NO language into the specification (as incorporated by reference from the publications) and the claims.

Applicants argue that if additional mutase or epimerase genes are encompassed by the claims, one of ordinary skill in the art would be able to utilize such genes. While the Examiner does not disagree, this is a question of enablement and not written description, which is the pertinent rejection herein.

## **NEW ISSUES**

### ***Objections to the Specification***

18. The specification is objected to for inappropriate notation of an internet address. On page 48, lines 17-18, an internet address is cited in an unacceptable form. See M.P.E.P. § 707.05(e) for the acceptable notation of an internet address.

19. The specification is objected to for having an incomplete reference. On page 91, reference 15 is incomplete and confusing as such. Appropriate correction is required.

### ***Summary of Pending Issues***

20. The following is a summary of the issues pending in the instant application:

- a) Figures 2-9 are informal.
- b) The specification stands objected to for inappropriate notation of an internet address
- c) The specification stands objected to for having an incomplete reference
- d) Claims 1, 17, 24, and 26-39 stand under 35 U.S.C. § 112, first paragraph, written description.



Art Unit: 1652

***Conclusion***

21. Claims 1, 17, 24, and 26-39 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

February 20, 2003

